Kimberly-Clark

April 21, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

99N-0970 '99 APR 27 P1:53

RE: [Docket No. 98N-0970] Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency

Kimberly-Clark Corporation has reviewed the proposed rule published January 21, 1999 (FR Volume 64, Number 13). In the proposed rule, FDA proposed to amend its menstrual tampon labeling regulation to provide an absorbency term for tampons that absorb 15 to 18 grams (g) of fluid and to enable consumers to compare the absorbency of one brand and style of tampons with the absorbency of other brands and styles. Kimberly-Clark appreciates the opportunity to comment and has participated in the development of the comments presented by INDA, the Association of the Non-woven and Disposable Fabrics Industry, and would also like to present the following independent comments.

Kimberly-Clark feels that the term "Ultra" may be a confusing descriptor based on the following:

1. The current descriptors for tampon absorbency are junior, regular, super and super plus, which are regulated by FDA and descriptive of the tampon's absorbency capacity. The term ' Ultra ' cannot be readily associated by consumers with the degree of absorbent capacity, instead, may imply performance superiority which may be misleading to consumers.

2. As consumers combine pad usage with tampons for their menstrual protection needs, the descriptors used in the pad segment may affect consumers' perception of the descriptors used in the tampon segment. For this purpose, the term ' Ultra ' could be confusing from consumers' standpoint because ultra is typically used to describe thinner pads, rather than thicker, higher absorbency products.

It is our opinion that "Extra" should be the alternative descriptor for 15-18 gram absorbency tampon because the term "Extra" is more neutral and simply descriptive of the tampon's absorbency capacity.

If there are questions, please contact me at (920) 721-3478.

Sincerely,

Brenda E. Nuite
Regulatory Affairs and Microbiology

cc: Colin M. Pollard, CDRH (HFZ-470), FDA, 9200 Corporate Blvd., Rockville, MD 20850

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